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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,696	03/09/2000	James Keith	22058-521	2455

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BOSTON, MA 02111

EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/521,696

Applicant(s)

KEITH ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 21 and 22 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-11, 21 and 22 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/5/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the amendment and response filed on 11/05/2003.

Claims 21 and 22 have been added. Thus, claims 1-11, 21 and 22 are pending.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

3. Applicants submission of an IDS is acknowledged.

Claim Rejections - 35 USC § 102, maintained

4. Claims 1,6 and 21 (newly added) remain rejected under 35 U.S.C. §102 (a) as being anticipated by Hill et al. (1998), is maintained for reasons set forth in Paper No: 19.

Applicant's arguments filed on 11/05/03 have been considered but are not persuasive.

Applicant disagrees with the position taken by the Office with respect to Hill reference inherently describing the claimed invention. Applicant contends that claim 1 requires the identification of a mammal at risk of developing complement-mediated cytotoxicity, and Hill fails to teach this limitation either explicitly or inherently. Unlike the Merck citation the Hill reference teaches a specific condition (GVHD) contemplated by the Applicant. Although, the Hill reference does not mention the complement-mediated cytotoxicity, it does treat a mammal at risk for GVHD. Furthermore, when the instant claims are read in light of the specification it is clear that the mammal at risk contemplated in the instant invention and the mammal treated in the Hill et al. reference have the same physiological condition, that is developing complement-mediated cytotoxicity. The specification clearly teaches that, "provided by the invention are methods of treating disorders where protection against CTL and/or complement-mediated cytotoxicity are

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shown to be beneficial including, without limitation, graft versus host disease (GVHD), and rejection of organ or tissue transplants (specification, page: 3, 2nd paragraph and page: 8, last paragraph). Therefore, identifying someone at risk for GVHD does meet the limitation of the claim of identifying them as at risk of complement-mediated cytotoxicity. Thus, it is clear that although, the prior art did not necessarily appreciate the mechanism by which the effect was attained, it clearly teaches the same method, using the same active agent (IL-11), as the rejected claims to treat GVDH caused by complement-mediated cytotoxicity associated with organ and tissue transplantation. The limitations present in claim 21 have already been addressed above. Therefore, claims 1, 6 and 21 remain rejected under 35 U.S.C. §102 (a) as being anticipated by Hill et al. (1998).

5. Claim 6 remains rejected under 35 U.S.C. §102 (b) as being anticipated by Yang et al. (U.S. Patent No. 5, 700,664). This rejection is maintained for reasons set forth in Paper No: 19 above in paragraph 4. Applicant's arguments filed on 11/05/03 have been considered but are not persuasive. Although, Applicant claims that Yang et al. fails to teach the claimed step of identifying a mammal with complement-mediated cytotoxicity, as indicated previously (Paper No: 19) above in paragraph 4, Yang et al. administer IL-11 to treat immune cell or hematopoietic cell deficiency following a bone marrow transplantation. When the instant claims are read in light of the specification it is clear that the mammal at risk contemplated in the instant invention and the mammal treated in the Yang et al. reference have the same physiological condition, that is developing complement-mediated cytotoxicity. The specification clearly teaches that, "provided by

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the invention are methods of treating disorders where protection against CTL and/or complement-mediated cytotoxicity are shown to be beneficial including, without limitation, graft versus host disease (GVHD), and rejection of organ or tissue transplants (specification, page: 3, 2nd paragraph, page: 8, last paragraph). Thus, treating complement-mediated cytotoxicity is inherent to IL-11. Therefore, the disclosure of Yang et al. anticipates instant claim 6.

Claim Rejections - 35 USC § 103, maintained

6. Claims 2-5, 7-11 and 22 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Hill et al. (1998) in view of Yang et al. (U.S. Patent No. 5,700,664) is maintained. Applicant's arguments filed on 11/05/03 have been fully considered but are not persuasive. Applicant's arguments with respect the references not teaching complement-mediated cytotoxicity has been addressed above in paragraphs 5, 6 and in Paper No: 19. Applicant also argues that the dose range of IL-11 administered is not suggested by Hill or Yang reference. Applicant agrees that Yang et al. teaches the administration of IL-11 in the range of 1-1000 µg/kg body weight for treating an immune disorder. Therefore, the limitation of 1-100 µg/kg body weight of IL-11 required for preventing or treating complement-mediated cytotoxicity (a immune disorder) associated with organ and tissue transplantation is within the limitation described by Yang et al. The limitations present in claim 22 have been addressed with respect to organ and tissue transplantation has been addressed above. Therefore, instant invention is obvious over Hill et al. (1998) in view of Yang et al. (U.S. Patent No. 5,700,664).

7. No claims are allowable over prior art.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

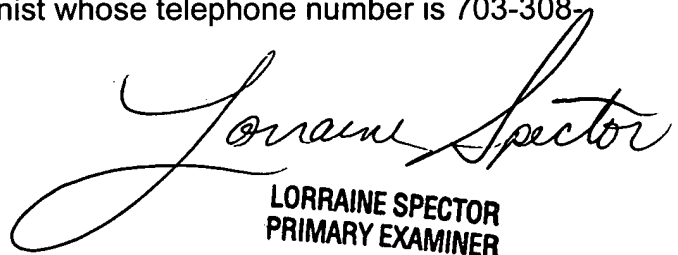
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


LORRAINE SPECTOR
PRIMARY EXAMINER

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